

Amendments to the Drawings

Figures 4A, 4B and 4D are amended to add the figures numbers 200, 208 and 210 that were cut off or illegible. Support for these changes can be found in the specification at paragraph [0100].

REMARKS

Claims 62, 66-68, 71, 74, 80, 81, 87, 88, 90-104, 106-108, 110-113, 115, 117, 118, 121, 123-125 and 131-161 are currently pending. Claims 1-65, 69, 70, 72, 73, 75-79, 82-86, 89, 109, 114, 116, 119, 120, 122, and 126-130 were cancelled. Claims 62, 66-68, 71, 74, 80, 81, 87, 88, 90-104, 106-108, 110-113, 115, 117, 118, 121, 123 and 124 are currently withdrawn from consideration as directed to a non-elected invention.

Claim 125 is currently amended and support can be found in the specification at Figure 1 and paragraph [0073]. Claim 141 is amended and support can be found, for example, in the specification at paragraph [0104]. New claims 162-167 are added. Claims 162 and 163 are claims 140 and 153 rewritten in independent form. Support for new claim 164 can be found, for example, in claim 155 and the specification at paragraphs [0075] and [0077]. Support for new claim 165 can be found, for example, in the specification at paragraph [0073]. Support for new claims 166 and 167 can be found for example in paragraph [0103].

35 USC 102 Rejection

Claims 125, 131-139, and 141-161 are rejected under 35 USC 102(b) as allegedly anticipated by U.S. Patent No. 4,927,408 to Haak et al. (“Haak”). Haak describes a transdermal system for delivery of a therapeutic that utilizes electrical current. The Examiner stated that “designing a structural element as ‘integral’ or ‘separable’ is an enhancement that does not merit patentability, and moreover, said enhancement should be considered an obvious alternative in the design process of the particular apparatus” (Office Action, page 3).

Haak describes a system which uses a galvanic couple, wherein the galvanic power electrodes provide power and are the patch electrodes. As such, Haak may describe electrodes integrally formed with a galvanic couple. However, Applicants argue the galvanic couple described by Haak and an electrochemical cell of the instant invention are not the same. The galvanic couple comprises donor 10 and counter 12 electrodes, contacting each other, but does not include an internal battery electrolyte in continuous contact with both the power source poles and wherein the power source poles are in spaced relation from each other. The circuit is closed when the system is placed on the skin, the body acting as an ion-conducting pathway. The

electrochemical cell of the instant application comprises two electrodes spaced apart and an electrochemical cell electrolyte.

The reference does further describe use of an additional power source in cases wherein the galvanic couple is insufficient (column 8, lines 4-11). However, the reference does not describe the electrodes being integrally formed with the additional power source such as a battery. As such, Haak does not disclose or teach instant claim 1.

The Examiner states that the case law on point regarding 'integral' established that designing a structural element as 'integral' or 'separable' is an enhancement that does not meet patentability and moreover said enhancement should be considered an obvious alternative in the design process of the particular apparatus. However, Applicants contend that there is conflicting case law regarding patentability of 'integral', which applies to the instant claim 125.

In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); but see *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which form "a single integral and gaplessly continuous piece." Nortron argued that the invention is just making integral what had been made in four bolted pieces. The court found this argument unpersuasive and held that the claims were patentable because the prior art perceived a need for mechanisms to dampen resonance, whereas the inventor eliminated the need for dampening via the one-piece gapless support structure, showing insight that was contrary to the understandings and expectations of the art.).

Applicants argue that Haak describes devices that are separable or not integrally formed, which include electrodes directly or indirectly connected by conventional means to power sources. When manufacturing patches it is advantageous to use as few components in order to simplify the production and lower the price of the product. The claimed device wherein the electrode is integrally formed with the battery such as by printing the electrode onto the respective battery pole or by using the battery terminal as the electrode eliminates the need for conventional connection means or even any connection means. This claimed device therefore provides a patch with less components than separable devices. In addition, the connection by

conventional means between the power source and electrode may restrict the minimal size of the devices, which may be critical when making devices for treating small body regions. The size and thickness of an integrally formed device may be minimal.

Further, functional differences result from the integral configuration. Conventional attachable electrodes using conventional connection means may detrimentally affect the current provided to the electrodes by lowering of the conductivity due to resistance at the connection points. The claimed device, wherein the electrode is integrally formed with the battery such as by printing the electrode onto the respective battery pole or by using the battery terminal as the electrode, eliminates the need for conventional connection means, which may facilitate providing optimal current. This integral battery electrode configuration is not separable as there are no electrode connection means to disconnect from. The art describes a need to connect a patch electrode to a pole of a battery with a connection means and therefore a patch wherein the patch electrode is applied to the battery pole without additional connection means in an integral configuration shows insight that was contrary to understanding of the art.

Further, the instant claim 125 includes an electrode being integrally formed with the power source wherein the electrode is part of the power source, such as the terminal of the power source. This configuration is not separable, because the terminal is substantially essential to the power source. The case law cited by the Examiner therefore does not apply to an electrode integrally formed with a power source, such as at least one of the electrodes being a terminal of the electrochemical cell. This configuration eliminates an element from the device as there is no need for both battery terminals and device electrodes. Haak describes a device wherein a power source is positioned between the donor electrode and counter electrode (column 8, lines 4-11), but does not describe or teach an electrochemical cell including terminals wherein at least one or two of the device electrodes is a terminal of an electrochemical cell as in claim 151 and claim 152.

With respect to claim 139, Applicants submit Haak does not teach use of a thin and flexible electrochemical cell. Furthermore, Applicants submit Haak does not teach a thin flexible open cell electrochemical cell, as recited in new independent claim 165.

With respect to claim 153, Applicants submit Haak does not describe a patch that is foldable. New independent claim 163 had been added.

With respect to claim 154, Applicants submit Haak does not describe a patch with only two electrodes and a power source wherein an electrode is integrally formed with the power source.

With respect to claim 155, Applicants submit Haak does not describe or teach the patch wherein the cell and the electrodes are printed onto the patch. Still further Haak Applicants submit does not describe or teach the patch wherein at least one electrode is printed onto the cell. New independent claim 164 has been added.

Conclusion

Although no fees are believed to be due, the Office may charge any additional fees required, or credit any overpayments, to Deposit Account No. 11-0600. The Examiner is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

Respectfully submitted,

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